UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

13

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,574	07/16/2002	Wolf Bertling	10848-018001	7496

7590 01/25/2007

Mark S Ellinger
Fish & Richardson
Suite 3300
60 South Sixth Street
Minneapolis, MN 55402

EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/049,574	BERTLING, WOLF	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-14,24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-5,7-10,24 and 25* is/are allowed.

6)☒ Claim(s) *11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed 01/17/06 is acknowledged and has been entered.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

1. The disclosure is objected to because of the following informalities: The disclosure fails to provide the following headings: BRIEF SUMMARY OF THE INVENTION, BRIEF DESCRIPTION OF THE DRAWINGS, and DETAILED DESCRIPTION OF THE INVENTION.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 11, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Furie et al (US 4,769,320).

Furie et al disclose a kit (col 26). Furie et al disclose an antibody specific for a carboxylated protein. Furie et al also disclose an antibody specific for decarboxylated protein (col 12 and col 27). Furie et al disclose that the antibodies can be labeled and placed into a kit (col 26). Furie et al disclose that the protein is prothrombin.

With respect to claim 12, Furie et al disclose that the label can be an enzyme (col 4).

With respect to the recitation "for carrying out the method as claimed in claim 1" this is intended use of the kit and a recitation of intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art and since Furie et al disclose the

same components as the instantly recited claims, Furie et al reads on the instantly recited claims and is capable of performing the method. Further, since Furie et al disclose the same components as recited in the kit the labeled antibodies of Furie et al would be able to generate a combined signal.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Furie et in view of Akhavan-Tafti et al (US 5,843,666).

See above for the teachings of Furie et al.

Furie et al differ from the instant invention in failing to specifically teach the combined signal is a combined color.

Akhavan-Tafti e al disclose a first antibody labeled with alkaline phosphatase and a second antibody labeled with horseradish peroxidase. Akhavan-Tafti et al disclose

that the combined action of the of both the hydrolytic enzyme and the peroxidase enzyme, operates to produce a detectable chemiluminescent signal (color). Akhavan-Tafti et al teaches that the use of these labels provides for methods to detect and quantitate with improved specificity various biological molecules including antigens and antibodies by the technique of immunoassay.

It would have been obvious to one of ordinary skill at the time the invention was made to incorporate labels as taught by Akhavan-Tafti et al with the antibodies and kit of Furie et al because Furie et al specifically teaches that the immunoassay can be enzyme-linked assays and because Akhavan-Tafti et al teaches that the use of these labels provides for methods to detect and quantitate with improved specificity various biological molecules including antigens and antibodies by the technique of immunoassay.

Allowable Subject Matter

Claims 1-5, 7-10, 24 and 25 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record neither teaches nor suggests a method for indirectly determining blood clotting status INR (International Normalized Ratio) as currently recited. See previous office action for closest art.

Response to Arguments

Applicant's arguments filed 01/17/06 have been fully considered but they are not persuasive.

Applicant argues that the antibodies described by Furie et al are "incorporated into two separate immunoassays" and that in contrast claim 11 requires that the first and second antibodies are each conjugated to a labeling substance, and that such labeling substances are selected such that they generate a combined signal that can be detected. This is not found persuasive because the Applicant is not on point with the argument. The instantly rejected claims are drawn to a kit comprising reagents to be used in assays. The currently recited claims are not directed toward assay methods or assays steps. Even, if Furie et al is teaching the reagents used in two separate assays, Furie et al clearly teaches antibodies specific for decarboxylated protein and antibodies specific for carboxylated protein and also teaches the antibodies can be labeled with enzymes and placed into a kit. Further, Furie et al is teaching the same reagents as recited by Applicant and teaches the same labels as recited by Applicant (i.e. enzymes). Therefore, the labeled antibodies of Furie et al would be capable of generating a combined signal.

Applicant further argues that Furie et al does not disclose that the labels on the first and the second antibody are selected such that they interact within one assay and generate a combined signal. This is not found persuasive because the interaction within one assay and generate a combined signal are intended use of labeled antibodies and as stated above the labeled antibodies are the same as recited by Applicant and therefore, would be capable of interacting within one assay and would also be capable of generating a combined signal.

Applicant argues that Akhavan-Tafti et al require using two different enzymatic reactions. The reaction disclosed by Akhavan-Tafti et al requires the action of both a hydrolytic enzyme and a peroxidase enzyme, which are maintained in close proximity to each other, to create chemiluminescent color. In contrast, claim 11 recites that the "combined signal represent C1 + C2. This is not found persuasive because of reasons stated above and further because even though Akhavan-Tafti et al requires two different enzymes, the currently recited claims do not excluded two different enzymes. Further, the enzymes as disclosed by Applicant are generic. Also, the recitation "combined signal represents C1 + C2" is intended use of the labeled antibodies within a method and as stated above the claims are directed to a kit and not methods steps or method assays.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
March 23, 2006

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
03/31/06